UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *The City of New York v. Abbott Labs., et al.* (S.D.N.Y. No. 04-CV-06054) *County of Nassau v. Abbott Labs, et al.* (E.D.N.Y. No. 04-CV-05126) and other cases listed on the following page	

MEMORANDUM OF MERCK & CO., INC. IN RESPONSE TO PLAINTIFFS' "NOTICE OF SUPPLEMENTAL AUTHORITY IN OPPOSITION TO MERCK'S MOTION TO DISMISS"

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December 11, 2006

THIS DOCUMENT RELATES TO:)	*County of Cortland v. Abbott Labs, et al.*)
The City of New York v. Abbott Labs., et al.)	(N.D.N.Y. No. 05-CV-00881))
(S.D.N.Y. No. 04-CV-06054))	*County of Herkimer v. Abbott Labs, et al.*)
County of Suffolk v. Abbott Labs., et al.)	(N.D.N.Y. No. 05-CV-00415))
(E.D.N.Y. No. 03-CV-229))	*County of Oneida v. Abbott Labs, et al.*)
County of Westchester v. Abbott Labs., et al.)	(N.D.N.Y. No. 05-CV-00489))
(S.D.N.Y. No. 03-CV-6178))	*County of Fulton v. Abbott Labs, et al.*)
County of Rockland v. Abbott Labs., et al.)	(N.D.N.Y. No. 05-CV-00519))
(S.D.N.Y. No. 03-CV-7055))	*County of St. Lawrence v. Abbott Labs, et al.*)
County of Putnam v. Abbott Labs, et al.)	(N.D.N.Y. No. 05-CV-00479))
(S.D.N.Y. No. 05-CV-04740))	*County of Jefferson v. Abbott Labs, et al.*)
County of Dutchess v. Abbott Labs, et al.)	(N.D.N.Y. No. 05-CV-00715))
(S.D.N.Y. No. 05-CV-06458))	*County of Lewis v. Abbott Labs, et al.*)
County of Washington v. Abbott Labs, et al.)	(N.D.N.Y. No. 05-CV-00839))
(N.D.N.Y. No. 05-CV-00408))	*County of Chautauqua v. Abbott Labs, et al.*)
County of Rensselaer v. Abbott Labs, et al.)	(W.D.N.Y. No. 05-CV-06204))
(N.D.N.Y. No. 05-CV-00422))	*County of Allegany v. Abbott Labs, et al.*)
County of Albany v. Abbott Labs, et al)	(W.D.N.Y. No. 05-CV-06231))
(N.D.N.Y. No. 05-CV-00425))	*County of Cattaraugus v. Abbott Labs, et al.*)
County of Warren v. Abbott Labs, et al.)	(W.D.N.Y. No. 05-CV-06242))
(N.D.N.Y. No. 05-CV-00468))	*County of Genesee v. Abbott Labs, et al.*)
County of Greene v. Abbott Labs, et al.)	(W.D.N.Y. No. 05-CV-06206))
(N.D.N.Y. No. 05-CV-00474))	*County of Wayne v. Abbott Labs, et al.*)
County of Saratoga v. Abbott Labs, et al.)	(W.D.N.Y. No. 05-CV-06138))
(N.D.N.Y. No. 05-CV-00478))	*County of Monroe v. Abbott Labs, et al.*)
County of Columbia v. Abbott Labs, et al.)	(W.D.N.Y. No. 05-CV-06148))
(N.D.N.Y. No. 05-CV-00867))	*County of Yates v. Abbott Labs, et al.*)
Essex County v. Abbott Labs, et al.)	(W.D.N.Y. No. 05-CV-06172))
(N.D.N.Y. No. 05-CV-00878))	*County of Niagara v. Abbott Labs, et al.*)
County of Chenango v. Abbott Labs, et al.)	(W.D.N.Y. No. 05-CV-06296))
(N.D.N.Y. No. 05-CV-00354))	*County of Seneca v. Abbott Labs, et al.*)
County of Broome v. Abbott Labs, et al.)	(W.D.N.Y. No. 05-CV-06370))
(N.D.N.Y. No. 05-CV-00456))	*County of Orleans v. Abbott Labs, et al.*)
County of Onondaga v. Abbott Labs, et al.)	(W.D.N.Y. No. 05-CV-06371))
(N.D.N.Y. No. 05-CV-00088))	*County of Ontario v. Abbott Labs, et al.*)
County of Tompkins v. Abbott Labs, et al.)	(W.D.N.Y. No. 05-CV-06373))
(N.D.N.Y. No. 05-CV-00397))	*County of Schuyler v. Abbott Labs, et al.*)
County of Cayuga v. Abbott Labs, et al.)	(W.D.N.Y. No. 05-CV-06387))
(N.D.N.Y. No. 05-CV-00423))	*County of Chemung v. Abbott Labs, et al.*)
County of Madison v. Abbott Labs, et al.)	(W.D.N.Y. No. 05-CV-06744))
(N.D.N.Y. No. 05-CV-00714))	*County of Ulster v. Abbott Labs, et al.*)
County of Cortland v. Abbott Labs, et al.)	(N.D.N.Y. No. 06-CV-00123))
(N.D.N.Y. No. 05-CV-00881))	
County of Wyoming v. Abbott Labs, et al.)	
(W.D.N.Y. No. 05-CV-06172))	

MEMORANDUM OF MERCK & CO., INC. IN RESPONSE TO PLAINTIFFS' "NOTICE OF SUPPLEMENTAL AUTHORITY IN OPPOSITION TO MERCK'S MOTION TO DISMISS"

Defendant Merck & Co., Inc. ("Merck") submits this memorandum in response to Plaintiffs' attempt to supplement their opposition to Merck's motion to dismiss the Consolidated Complaint of New York City and Plaintiff New York Counties Other Than Nassau (the "Consolidated Complaint").

INTRODUCTION

On November 1, 2006, more than four months after the June 16, 2006 hearing on dismissal, Plaintiffs, without seeking leave or explaining their delay, filed a Notice of Supplemental Authority In Opposition to Merck's Motion To Dismiss, appending a May 31, 2006 decision from the United States District Court for the District of Nevada, *Nevada, ex rel. Steinke v. Merck & Co., Inc.*, 432 F. Supp. 2d 1082 (D. Nev. 2006) ("*Steinke*"). This Court need not and ought not consider Plaintiffs' submission – an order denying a motion to dismiss a complaint that asserts different claims by a different plaintiff.[1]

In the event this Court decides to consider the *Steinke* decision, the Court should recognize that the decision rests on a fundamentally mistaken interpretation of the nominal price exclusion from Best Price under the federal Medicaid Rebate Act and Rebate Agreement. In fact, Merck has asked the Nevada District Court to reconsider the *Steinke* decision, based on, *inter alia*, subsequent federal administrative guidance that further supports Merck's exclusion of nominal prices. Although the *Steinke* court has not ruled on Merck's

[1] Separate and apart from the deficiencies described below, the *Steinke* decision has no bearing on the myriad legal shortcomings of the Consolidated Complaint. Among other things, the *Steinke* case was a *qui tam* action brought on behalf of the State of Nevada, which does not present the same problems related to standing as do the New York Counties' claims. *See In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 339 F. Supp. 2d 165 (D. Mass. 2004).

reconsideration motion, the new federal guidance confirms what was already clear – the decision is erroneous and should not be followed.

1. The *Steinke* Decision Is Erroneous And Should Not Be Followed

The law is clear that manufacturers are *required* to *exclude* from Best Price any price less than 10% of Average Manufacturer Price ("AMP").[2] The Medicaid Rebate Statute provides that a manufacturer's reported Best Price "shall not take into account prices that are merely nominal in amount." 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(III). In promulgating the federal Rebate Agreement for use with each manufacturer participating in the Medicaid Rebate program in 1991, the Secretary of Health and Human Services defined "nominal price" to be "any price less than 10% of the AMP in the same quarter for which the AMP is computed." Rebate Agreement § I(s) (Ex. A). Likewise, in 1994, the Centers for Medicare and Medicaid Services ("CMS"), the federal agency charged with administering the Medicaid program, gave express direction to manufacturers on how the nominal price exclusion under the Rebate Statute and the Rebate Agreement should be applied:

> Please remember that *any* prices which are nominal in amount, that is, *less than 10% of the AMP* in the same quarter which the AMP is computed, are excluded from the best price calculation. Therefore, if any arrangement results in prices which are nominal**,** those sales and prices do not affect best price and *must be excluded by the manufacturer*.

CMS Release No. 14, at 2 (emphasis added) (Ex. B).

Although the *Steinke* court purported to defer to the Secretary's interpretation of the prices to be excluded from Best Price, it did not apply the plain language of the Rebate

[2] The Deficit Reduction Act of 2005 amends the Rebate Statute effective January 1, 2007 to eliminate the exclusion of sales at nominal prices from Best Price except when such sales are made to certain specified types of purchasers ("safety net" providers), such as participants in the federal 340B Drug Discount Program or other entities as determined by the Secretary. *See* Pub. L. 109-171, Title VI, § 6001(d)(2), 120 Stat. 56, 58 (2006).

Agreement or the Secretary's administrative guidance. The plaintiff's complaint alleged that Merck had improperly excluded from its Best Price reports certain prices offered to hospitals as part of nominal pricing programs. Despite the fact that the prices Merck offered were indisputably less than 10% of AMP, the court denied Merck's motion to dismiss the claim. Instead of following the unambiguous language of the Rebate Agreement and the Secretary's 1994 guidance, which dictates that such prices be excluded from Best Price, the *Steinke* court decided that the Rebate Statute's exclusion of "prices that are merely nominal in amount" must be interpreted to mean "'all prices that are less than 10% of the AMP, but without other qualifications.'" *Steinke*, 432 F. Supp. 2d at 1087.

The *Steinke* court did not explain how its interpretation of the nominal price exclusion was consistent with the Secretary's express guidance in CMS Release No. 14 for excluding nominal prices. Instead, the court purported to rely on two agency statements for its interpretation of the nominal price exclusion from Best Price, even though those statements were not interpretations of that exclusion. *Steinke*, 432 F. Supp. 2d at 1087 (quoting letter from CMS Administrator and CMS Release No. 14). The CMS letter simply refers to the language of the separate part of the Best Price definition, which says that *free goods* contingent on *purchase requirements* shall be included in Best Price. Similarly, the quoted passage from CMS Release No. 14 observes – not in the context of commentary on nominal price – that Best Price must be adjusted if "other arrangements subsequently adjust the prices actually realized." *Id.* Neither the *Steinke* complaint nor the Consolidated Complaint suggest the existence of "other arrangements" that caused Merck to realize prices higher than 10% of AMP on its nominal price sales to hospitals.

Notably, the *Steinke* court also did not address amendments to the Rebate Statute by the Deficit Reduction Act of 2005, which will prospectively limit the nominal price exclusion to sales to "safety net" providers beginning January 1, 2007. *See* 42 U.S.C. § 1396r-8(c)(1)(D); *see also* H.R. Conf. Rep. No. 109-362, at 259-60 (describing "current law" prior to the amendment and stating that "[n]ominal prices are defined by CMS to be those that are below 10 percent of [AMP]," without reference to any other limitations). This amendment made clear that there is no difference between sales at a "nominal price" and sales that are "merely nominal in amount," and that the existing nominal price exclusion was in no way limited (as Plaintiffs in this proceeding have asserted) to charitable institutions. Congress plainly knows how to create such limitations, and has now done so prospectively.

In light of these errors and omissions, Merck respectfully submits that the *Steinke* court's interpretation of the Rebate Statute and Rebate Agreement is flawed and should not be adopted by this Court.

2. Subsequent Federal Administrative Guidance Confirms That The *Steinke* Decision Is Erroneous

In the *Steinke* proceeding, Merck has filed a motion for reconsideration based upon a proposed rule issued by CMS on August 7, 2006 under the Deficit Reduction Act of 2005 to implement Part B of the Medicare Program, which further demonstrates that the *Steinke* decision rests on an erroneous interpretation of the nominal price exclusion. The proposed rule sets forth a definition of "nominal sales" for manufacturers to use in calculating a drug's Average Sales Price ("ASP"). Nominal sales for purposes of Medicare Part B have the same definition as nominal sales under the Medicaid Drug Rebate Program. *See* 42 U.S.C. § 1395w-3a(c)(2)(B). In the proposed rule, CMS explains that, in identifying nominal sales that manufacturers must exclude from ASP, manufacturers should take the following steps:

> ***Consistent with current Medicaid reporting***, for 2005 and 2006, manufacturers must identify nominal sales by performing the following steps [one time]:
>
> - The manufacturer calculates the AMP for the reporting quarter to identify the dollar amount that represents 10 percent of the AMP for that reporting period.
>
> - The manufacturer then identifies sales below this amount and excludes these sales from the ASP calculation.

See Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B, at 103 (attached, in relevant part, as Ex. C) (emphasis added). Beginning in 2007, manufacturers must take an additional step to implement the new "safety net" provider limitations on nominal price sales under the Deficit Reduction Act, but there is still no requirement that manufacturers evaluate whether there are any "other qualifications" or contingencies (other than those that affect the price actually realized) attached to a price below 10% of AMP.

The proposed rule that is the subject of Merck's motion for reconsideration has become final, with no change to the steps required for calculation of nominal sales.[3] Accordingly, administrative guidance from both before and after the *Steinke* court's decision demonstrates that the *Steinke* court's interpretation of the Medicaid Rebate Statute and Rebate Agreement should not be followed.

[3] *See* Medicare Program Revisions to Payment Policies, 71 Fed. Reg. 69,624, 69,672 (Dec. 1, 2006). At this time, Merck does not anticipate an immediate decision on the motion for reconsideration because Merck and the other parties in the Nevada litigation have agreed to a stay of proceedings.

CONCLUSION

For the reasons set forth above and in Merck's memoranda in support of its Motion to Dismiss, this Court should dismiss the Consolidated Complaint as to Merck.

Dated: December 11, 2006

Respectfully submitted,

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